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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,955	MICHAL ET AL.	
	Examiner	Art Unit	
	Allison M Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 19-25, drawn to a method comprising identifying and delivering cells to an infarct region, classified in class 424, subclass 93.2.

II. Claims 9-18, 23-25, 35-44 and 51-60, drawn to a method comprising identifying and delivering electrical stimulation to an infarct region, classified in class 607, subclass 50.

III. Claims 26-32, drawn to a kit comprising a delivery lumen and at least one cell, classified in class 623, subclass 1.13.

IV. Claims 33-34, drawn to a method of detecting cellular transplant in heart, classified in class 424, subclass 9.6.

V. Claims 45-50, drawn to a composition, classified in class 427, subclass 212.

VI. Claims 61-62, drawn to a kit comprising a delivery lumen and a cardiac electrical device, classified in class 600, subclass 386.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and IV are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the methods have different steps. The method of Group I requires cells to be delivered to the infarct region, which is not required by any of the other methods. The method of Group II requires electrical stimulation to be applied to the heart and/or ventricle, which is not required by any of the other methods. The method of Group IV does not involve any step of identifying an infarct region, rather it is involves a step of detecting nucleic acids

and requires the use of fluorescence molecules, which is not required by any of the other methods. Therefore the different steps constitute distinct methodologies, each requiring non-coextensive searches.

Inventions III and VI are distinct inventions and thus are subject to restriction. The inventions are distinct in that the products are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the two kits have different components. The kit of Group III is required to comprise at least one cell, which is not required by the kit of Group VI; the kit of Group VI is required to comprise a cardiac electrical device, which is not required by the kit of Group III. Therefore the components of the two kits are separate and distinct, the search of kits comprising cells would not require a search of kits comprising electrical devices, similarly a search of kits comprising electrical devices would not require a search of kits comprising cells; thus the searches are not co-extensive and the products are deemed distinct and independent.

Inventions V is related to inventions I and II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Please note that claim 45 is drawn to "A. composition," it is not clear what this means, as the claim appears to be directed to a method; the claim is being interpreted to be directed to "A composition" comprising a bioerodible microparticle. Therefore, in the instant case a bioerodible microparticle can alternatively be used as a delivery device for medications, for example, bioerodible microparticle could be used to contain a pharmaceutical composition, so that when ingested the microparticle bioerodes and releases the pharmaceutical composition to act within the body.

Invention V is unrelated to inventions III, IV and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the composition of

Group V is not included in either of the kits of Groups III or VI. Additionally, the composition of Group V does not appear to be used in the method of Group IV, as the method does not involve any steps that would utilize a bioerodible microparticle.

The method of invention IV is unrelated to the kits of inventions III and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the method of invention IV does not use any of the elements included in either the kit of invention III or the kit of invention VI, as neither kit provides a means to detect at least one nucleic acid or a method of detecting fluorescence, as is required by the method of invention IV.

The method of invention I is unrelated to the kit of invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the kit of invention VI includes a cardiac electrical device, which is not required by or usable in the method of invention I.

The method of invention II is unrelated to the kit of invention III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the kit of invention III includes cells, which are not required by or usable in the method of invention II.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of invention III comprises genetically engineered α-1,3-galactosyltransferase and a delivery lumen, this kit can alternatively be used to for in vitro testing of compounds that can replace or restore the α-1,3-

galactosyltransferase activity; it is not required that the kit be used to deliver cells to an infarct region in the heart.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of invention VI can alternatively be used to implant a pacemaker, which would require delivery of a structural reinforcement to hold the pacemaker in place, and the electrical stimulation from a cardiac stimulation device which would be placed adjacent to the pacemaker. Therefore the components of the kit can be used in a materially different method than that of invention II.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Additionally, claims 1 and 9 were found to be linking claims; therefore upon the election of Group I or Group II, respectively, a further election of species will be required as follows:

Upon the election of Group I:

In this application Group I (claims 1-8 and 19-25) contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: (Claims 1-8 and 19-22) method involving applying a pacing algorithm for CRT

Species 2: (Claims 1-8 and 23-25) method involving applying electrical stimulation for peri -infarct induction

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the election of Group II:

In this application Group II (claims 9-18, 23-25, 35-44 and 51-60) contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: (Claims 9-18 and 23-25) method wherein structurally reinforcing component comprises cells

Species 2: (Claims 9 and 35-38) method wherein structurally reinforcing component comprises one or more solid material capable of increasing the compliance of the ventricle

Species 3: (Claims 9 and 39-40) wherein structurally reinforcing component comprises bioerodible particles

Species 4: (Claims 9 and 41-44) method wherein structurally reinforcing component comprises a scaffolding material

Species 5: (Claims 9 and 51-52) method wherein structurally reinforcing component comprises a first component comprising a biocompatible polymer-forming agent and a second component comprising a biocompatible perfluorinated moiety

Species 6: (Claims 9 and 53-54) method wherein structurally reinforcing component is delivered to the infarct border zone region

Species 7: (Claims 9 and 55-60) method wherein structurally reinforcing component comprises a modified and/or unmodified algenate gel material

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 9 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Furthermore, upon the election of **species 4 (Claims 9 and 41-44):** it is noted that claim 40 is generic to a plurality of disclosed patentably distinct species of growth promoting agents comprising bFGF, PDGF-BB, PDGF-AB, TGF-α, TGF-β1, 2, and 3, G-CSF, SCF, SDF-1, HGF, IGF, VEGF, TNF-α, angiogenin, angiopoiein-1, Del-1, follistatin, pleiotrophin, proliferin, transforming, and VPF. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the allowance of any of the generic claims (1, 9 or 40), applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious

variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai, In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**It is also noted that claim 45 is directed to "A. composition," while the body of the claim appears to be directed to a method. Similarly, claim 55 is directed to a method, while the body of the claim appears to be directed to an apparatus.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER